Message Text

UNCLASSIFIED

PAGE 01 STATE 028698 ORIGIN HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-06 /025 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK APPROVED BY OES/APT/BMP: WJWALSH, III DHEW/OIH: BROYSTER EUR/CE:KAKURZE(INFO) EUR/NE:JPSHUMATE(INFO) EUR/NE:REWOODS(INFO)

-----090519Z 104894 /21

R 090022Z FEB 77 FM SECSTATE WASHDC TO AMEMBASSY BONN AMEMBASSY LONDON AMEMBASSY STOCKHOLM AMEMBASSY HELSINKI

UNCLAS STATE 028698

E.O. 11652: N/A

TAGS: OTRA, OGEN, ETRD, TBIO, GW, UK, SW, FI

SUBJECT: FDA REPRESENTATIVE VISITING EUROPEAN X-RAY MANUFACTURERS.

- 1. FDA ADVISES THAT MR. DAVID R. SNAVELY, CHIEF STAND-ARDS AND TEST METHODS DEVELOPMENT, DIVISION OF COMPLIANCE AND MR. WILLIAM H. MIDGETTE, COMPLIANCE TEST AND EVALUATION OFFICER, DIVISION OF COMPLIANCE, BUREAU OF RADIOLOGICAL HEALTH WILL BE IN EUROPE MARCH 20-APRIL 1, 1977.
- 2. IN ACCORDANCE WITH THE DIAGNOSTIC X-RAY PERFORMANCE STANDARDS WHICH WAS MADE EFFECTIVE AUGUST 1, 1974 AND IN ACCORDANCE WITH GOOD MANUFACTURING PRACTICES THE TWO FDA REPRESENTATIVES WILL VISIT EIGHT FOREIGN DIAGNOSTIC X-RAY UNCLASSIFIED

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MANUFACTURERS TO DETERMINE IF THE FIRMS FACILITIES AND OPERATIONS ARE IN ACCORDANCE WITH THE AFOREMENTIONED ACT AND WILL REPORT ANY DEVIATIONS WHICH WILL HAVE AN ADVERSE EFFECT UPON EQUIPMENT THEY EXPORT TO THE UNITED STATES.

3. ITINERARY AS FOLLOWS:

MARCH 18, 1977: DEPART ROCKVILLE, MARYLAND FOR HAMBURG, WEST GERMANY

 $\label{eq:march21} \textbf{MARCH21,1977: VISIT PHILIPS MEDICAL SYSTEM HAMBURG, WEST GERMANY}$

MARCH 22, 1977: DEPART HAMBURG, WEST GERMANY FOR LONDON, ENGLAND

MARCH 22, 1977: VISIT DEPARTMENT OF HEALTH AND SOCIAL SECURITY (U.K. MINISTRY OF HEALTH)

MARCH 23, 1977: VISIT EMI LONDON, ENGLAND

MARCH 24, 1977: VISIT PANTEK LONDON, ENGLAND

MARCH 25, 1977: VISIT TODD RESEARCH INC., LONDON, ENGLAND

MARCH 26, 1977: TRAVEL LONDON, ENGLAND TO STOCKHOLM, SWEDEN

MARCH 28, 1977: TRAVEL STOCKHOLM, SWEDEN TO LINKOPING

MARCH 28, 1977: VISIT SAAB-SCANIA LINKOPING

MARCH 28, 1977: TRAVEL TO STOCKHOLM FROM LINKOPING

MARCH 28, 1977: VISIT SIEMANS-ELENA, STOCKHOLM, SWEDEN UNCLASSIFIED

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MARCH 30, 1977: TRAVEL STOCKHOLM TO HELSINKI, FINLAND

MARCH 30-31, 1977: VISIT PALOMEX, HELSINKI

APRIL 1, 1977: DEPART FINLAND FOR UNITED STATES

4. ASSISTANCE OF EMBASSIES WILL NOT BE REQUIRED. VANCE

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NNN

Message Attributes

Automatic Decaptioning: X

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Disposition Approved on Date: Disposition Case Number: n/a Disposition Comment:

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Subject: FDA REPRESENTATIVE VISITING EUROPEAN X-RAY MANUFACTURERS.

TAGS: OTRA, OGEN, ETRD, TBIO, GE, UK, SW, FI, (SNAVELY, DAVID R)
To: BONN LONDON MULTIPLE

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